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(54) **Investment casting**

(57) Methods are provided for producing investment cast articles, such as orthopedic implants, or portions thereof, having at least a partially textured surface that is formed during casting of the article. In an exemplary method, a textured metal casting is produced by creating a heat destructible pattern and spraying the pattern with a texturing material to cause the texturing material to form a textured surface on at least a portion of the pattern. In another embodiment, a textured template is pressed against a heat softenable pattern to provide a

textured pattern. With respect to each of these methods, a shell is created around the textured pattern to form a mold, and the pattern is removed from the shell. Molten metal is introduced into the mold and allowed to harden, after which the mold is removed. In yet another embodiment a textured pattern for investment casting is provided by creating a textured model and enveloping it with a resilient material to create a resilient mold. The textured model is removed from the resilient mold and the mold is filled with investment casting wax to create a textured pattern.

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Description**Field of the Invention**

The present invention relates to investment casting, and more particularly to the manufacture of investment cast articles, such as orthopedic implants, with a textured surface.

Background of the Invention

Various metal casting processes, such as investment (or "lost wax") casting are well known for the fabrication of metal objects. This process requires several steps, the first of which is to create or provide a pattern or shape to be replicated. The pattern, often made of wax, is used to make a mold that is then used to form cast metal articles.

Typically, several wax patterns are joined together on a wax "tree" to enable the simultaneous manufacture of several parts. The tree is a solid wax tube that has side walls to which a stem of each wax pattern is joined to form a cluster. The wax tree defines what will become a gate leading to passages for allowing molten metal to travel through the mold to each cluster and part pattern. Once all of the wax patterns are joined to the wax tree, the cluster is coated with one or more coats of a refractory by dipping the wax pattern-tree assembly in a ceramic slurry. After the slurry dries, fabrication of a shell or mold is completed by heating the slurry coated wax to cure or harden the ceramic, and to melt out the solid wax patterns and the wax tree. Molten metal is then poured into the shell so that it fills each of the cavities formerly occupied by the wax patterns and the wax tree. After the metal has cooled and hardened, the shell is fractured and removed, and the cast metal parts are severed from the metal tree. The cast parts are then subjected to post-machining, grinding off the gates, bead blasting, and polishing, as required.

With respect to medical implants, such as joint prosthesis components, it has been discovered that texturing or roughening the surface of a cast metal implant can improve the interface and fixation between the implant and the bone, with or without bone cement. The creation of a roughened surface on an implant, whether it was investment cast or forged, is typically one of the last steps in the manufacturing process of the component. Known methods for obtaining a roughened surface include grit-blasting, grinding, direct machining, laser etching, and sintering of beads to the surface of the implant.

Known surface texturing techniques, however, have severe short-comings with respect to manufacturing speed, efficiency, and cost, as well as structural limitations and deficiencies. For example, if the surface of the implant is improperly roughened, the final finished implant must be discarded. Depending on the alloy used to fabricate the implant and the size of the implant, the

creation of unacceptable texturing can significantly increase manufacturing cost. The creation of a textured surface requires a skilled craftsman. Therefore, for other than simple, uniform texturing, precise replication of a particular configuration is difficult to achieve in even limited production quantities. Furthermore, known surface texturing techniques are incapable of creating certain complex shapes and patterns, such as undercutting, which foster bone ingrowth and more secure fixation. Yet another disadvantage of known techniques for texturing a previously-cast implant is that the application of texturing materials, such as with a plasma-spray process results in an imperfect bond between the sprayed-on material and the implant which can lead to abrasive detachment and weak substrate coating interfaces. Similarly, sintering beads on a surface causes loss of favorable mechanical properties of the implant.

Summary of the Invention

The present invention overcomes the disadvantages of known surface texturing techniques by providing a heat destructible pattern having a textured surface. The textured pattern is used to create an investment casting mold which in turn is used to create the cast article. This technique allows very specific and/or complex patterns to be integrally formed with the implant surface as cast.

In an exemplary method, a textured metal casting, such as an orthopedic implant or a component thereof, is produced by creating a heat destructible pattern and spraying the pattern with a texturing material to cause the texturing material to form a textured surface on at least a portion of the pattern. The texturing material can include molten wax droplets that adhere to and/or melt at least a portion of the surface of the pattern or solid particles that adhere to and/or indent the surface of the pattern. The texturing material can be evenly or unevenly sprayed against the at a selected temperature and velocity to create a desired texture. A shell is created around the textured pattern to form a mold, and the pattern is removed from the mold. Molten metal is introduced into the mold and allowed to harden, after which the mold is removed from the textured casting.

In another embodiment, a textured template is pressed against a heat softenable pattern to provide a textured pattern. The textured template can be formed by creating a data file that defines a three-dimensional textured template; providing the data file to a rapid prototyping machine; and forming a model representative of the three-dimensional textured template with the rapid prototyping machine. A second textured template can be provided that has a different texture than the first textured template.

In yet another embodiment, a textured pattern for investment casting is provided by creating a textured model and enveloping it with a resilient material, such as silicon, to create a resilient mold. The textured mod-

It is removed from the resilient mold and the mold is filled with investment casting wax to create a textured pattern. The textured model can be fabricated with a rapid prototyping machine that performs stereolithographic operations, which enable the model to include very complex geometries, as well as undercuts, that are particularly well suited for bone ingrowth.

Brief Description of the Drawings

A more complete understanding of the present invention and the attendant advantages and features thereof will be more readily understood by reference to the following detailed description when it is considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a simplified illustration of a pattern being sprayed with a texturing material;

FIG. 2 is a sectional view of a portion of a pattern having wax spray texturing to create positive relief features;

FIG. 3 is a sectional view of a portion of a pattern having wax spray texturing to create negative relief features;

FIG. 4 is a sectional view of a portion of a pattern having solid particle texturing;

FIG. 5 is a schematic view of a pattern being textured with a template;

FIG. 6 is a schematic illustration of the creation of a model using a computer-assisted design system;

FIG. 7 is a schematic illustration of a rapid prototyping machine making an object corresponding to a computer-assisted design model of FIG. 6;

FIG. 8 is an illustration of the object of FIG. 7 encased in a resilient material; and

FIG. 9 is a perspective view of one-half of a soft mold.

Detailed Description of the Invention

A first embodiment of a method of making a textured investment casting begins with the step of creating a custom heat destructible pattern or selecting an existing pattern from stock supplies. Typically, patterns are made of investment casting wax, however, many plastics are also acceptable, as are hybrid wax/plastic patterns. As used herein, a "pattern" is full-scale representation or model of any article that is either machine or handmade. Exemplary patterns include components for

orthopedic implants and portions thereof.

After the pattern is selected or created, a heat destructible texturing material is selected for spraying against the pattern. Exemplary texturing materials include wax droplets or beads that are molten, soft, or hard, and plastic particles or beads. However, any material which may be applied to the pattern and which will subsequently burn out of a mold cleanly may be used. As used herein, "particle" or "droplet" is intended to encompass any size or shape configuration obtainable with a given texturing material, and the particular size and configuration or morphology of a selected particle or droplet is selected to achieve a desired texture.

Following selection of a texturing material, a spray is created with the texturing material and it is directed toward the pattern or the pattern is placed in the path of the spray. As used herein, a "spray" is intended to encompass everything from a concentrated, narrow stream to a diffuse mist, and "spray" should be broadly construed to mean placing the texturing material or a portion thereof in motion. The particular dispersion, concentration, temperature, and pressure of the spray are determined by the texturing material and the desired texture for the pattern. As illustrated in FIG. 1, molten wax or solid particles 10, such as wax or plastic beads under pressure can be ejected from a nozzle 12 to create a spray. A pattern 14 is shown in the path of the spray.

FIG. 2 illustrates a pattern 14 that has been sprayed by molten wax droplets, wherein the molten wax temperature and spray velocity were such that at least some of the molten wax droplets adhered to at least a portion of the surface 16 of the pattern to create surface texturing, roughness, or bas relief. In FIG. 2, the droplets have been deposited to form bumps that can be defined as positive surface relief features, on a portion of the pattern surface 16.

FIG. 3 illustrates a pattern 14 that has been sprayed by molten wax droplets, wherein the molten wax temperature and spray velocity were such that at least some of the molten wax droplets melted away at least a portion of the surface 16 of the pattern to create surface texturing, roughness, or bas relief. In FIG. 3, the droplets have been created depressions, voids, or indentations 20 that can be defined as negative surface relief features, on a portion of the pattern surface 16.

The temperature of the spray of molten wax can be regulated to create positive and negative surface features in the same surface areas. Also, the spray of texturing material can be directed toward the pattern 16, or a portion thereof, to evenly or unevenly distribute the spray to create, respectively, a substantially uniform or irregular pattern. Furthermore, although the bumps 18 and indentations 20 appear rounded in the illustrations, their shapes can range from circular to linear, and the bumps and indentations can have angled or convoluted boundaries.

FIG. 4 illustrates a pattern 22 that has been sprayed

by solid particles 24, wherein the particle temperature, spray velocity, and particle morphology were such that at least some of the particles adhered to at least a portion of the surface 26 of the pattern 22 to create surface texturing, roughness, or bas relief. The particles 24 form bumps 28 that can be defined as positive surface relief features, on a portion of the pattern surface 26. The particles can range from being barely to fully impacted in the surface of the pattern. Bumps are also created by the displacement of pattern material in response to particle impact.

FIG. 4 also illustrates additional surface texturing, roughness, or bas relief in the form of depressions, voids, or indentations 30 that can be defined as negative surface relief features. These indentations are created by impact of the particles 24 with the surface 26 and then bouncing off or not adhering to the surface. As with respect to the molten wax spray technique, the temperature of the particulate spray can be regulated to create positive and negative surface features in the same surface areas. Similarly, the particulate spray of texturing material can be directed toward the pattern 22, or a portion thereof, to evenly or unevenly distribute the spray to create, respectively, a substantially uniform or irregular pattern. Furthermore, although the bumps 28 and indentations 30 appear rounded in the illustrations, their shapes can range from circular to linear, and have angled or convoluted boundaries. If the particles impact the surface at an angle, an under-cut surface 32 is created.

Yet another technique for creating a textured pattern includes pressing a textured template 34 against at least a portion of a heat softenable pattern 36 to provide a textured pattern, as shown in FIG. 5. Either the textured template 34, the pattern 36 or both can be heated to facilitate pattern creation. Alternatively, the template can create a texture on the pattern by pressing the template against the pattern with enough pressure to deform the pattern. This technique is well suited for applications requiring a precise and/or complicated pattern geometry, and it is particularly well suited for providing a texture that promotes bone ingrowth.

In an exemplary embodiment, the template 34 is a metal object fabricated using any known technique for creating a metal object. Alternatively, the template 34 can be fabricated from a plastic that has a higher melting/distortion point than the wax pattern. However, in other embodiments, the template is created with a rapid prototyping machine. The object created by the rapid prototyping machine can itself be used as the textured template, or it can be used as a model for the creation of an investment casting mold.

For example, a textured template can be provided by creating a data file that defines a three-dimensional textured template, wherein the textured template includes a texture pattern configured to promote bone ingrowth. The data file is provided to a rapid prototyping machine capable of creating a heat destructible model

or a ceramic model. A heat destructible model representative of the three-dimensional textured template is then created with the rapid prototyping machine. A heat resistant shell is formed around the heat destructible model and heat is applied to the shell to remove the heat destructible model therefrom. Molten metal is poured into the shell; the molten metal hardens; and the shell is removed. The thus formed textured template is heat pressed against at least a portion of the pattern to provide a textured pattern. A second textured template having a different texture than the first textured template can be provided and pressed on at least a portion of the pattern to provide a pattern with different textures on different regions thereof.

Each of the above techniques provides different manufacturing advantages. However, should a problem be encountered in the texturing steps, the cost associated with scrap is greatly reduced as only inexpensive wax is sacrificed rather than a nearly finished product. Accidentally roughened surfaces of a wax pattern are easily smoothed by heating the wax.

Having been imparted with a surface texture, the pattern, created by whatever method, is used to create a mold. In an exemplary method, the pattern is coated with particles of a refractory material by spraying or dipping to create a shell around the textured pattern. The textured pattern is removed from the shell by the application of heat which causes the pattern, and any blast media impacted thereon, to melt, burn, or vaporize, allowing it to be drained or exhausted from an opening in the shell. Heating, either in this or a subsequent step, cures the refractory material to complete the mold making process.

Subsequent casting steps are not discussed in great detail, as they are well known to those skilled in the art of metal casting. These steps include introducing molten metal, such as Cr-Co-Mo alloy (ASTM F75) through one or more gates in the mold. The mold and the metal are allowed to cool, and the mold is removed from the hardened metal. The textured implant can then be subjected to post-machining, grinding off of gates, bead blasting, and polishing, as required.

Yet another embodiment of the invention is illustrated by FIGS. 6-9, wherein a textured pattern for investment casting is provided by creating a textured model and enveloping it with a resilient material to create a resilient mold. The method begins by creating a textured model, and although the textured model can be created by any of the techniques discussed above, a model created with a rapid prototyping machine is particularly advantageous as it permits fabrication of configurations and textures not obtainable by conventional methods.

Referring now to FIG. 6, an input device 40, such as a keyboard, mouse, light pen, and the like, is associated with a computer 42 and a display unit 44, to facilitate the creation of a data file that defines a three-dimensional article 46 representative of at least a portion of a bioimplantable article. The data file can be cre-

ated by any of a number of drawing, graphic, design, or solid modeling programs known to those skilled in the art. An exemplary computer aided design program (CAD) is "Pro Engineer," available from Parametric Technology Corporation. The data file can also define bleeders and gates used in casting as required.

By initially creating the article 46 as a CAD model, the article can be reviewed "on screen" or as computer generated drawings by a surgeon/engineer and modified as required prior to actually creating a mold or an implant. To further improve the review and design process, a three-dimensional model can be fabricated to assess potential modifications. Furthermore, the complexity and subtlety of the model is greatly enhanced. Special contoured surfaces, undercuts, internal cores, or typically machined features, as well as other features that are not machineable, can be easily incorporated into a CAD model and built with a rapid prototyping machine due to its layered fabrication capability.

In a subsequent step, a data file 48 that has been created as described above is provided to, or accessed by, a rapid prototyping machine 50 capable of transforming the data into a tangible object 52. Exemplary rapid prototyping machines include: selective laser sintering, solid ground curing, fused deposition modeling, Stereolithography, LOM, and three-dimensional printing.

In an exemplary embodiment of the method, the data defines a biocompatible article having a surface configuration that promotes bone ingrowth. For example, the article can include several discrete layers each having a different configuration and/or porosity. These layers can have a 10% to 20% porosity difference from layer to layer. Also, the article can include different regions, wherein the porosity is different in each region. Although there are many ways to configure the surface to make it porous, an exemplary article is defined to include generally round or oval pores that provide openings in the surface of the article, such as an orthopedic implant. The pores are in the range of 50 to 400 microns in diameter and have a depth in the range of 175 to 1,000 microns; and the implant surface can have an open porosity in the range of 30% to 70% of its total surface area.

After the textured article or model 52 has been fabricated by whatever method, a resilient material 54, such as room temperature vulcanization (RTV) silicone is applied to the model to envelop it, thus creating a resilient mold of the textured model as shown in FIG. 8. Prior to envelopment, one or more dividers 56 or partitions can be placed around the model to create one or more parting lines in the mold in a manner known to those skilled in the art, which allows the mold to be separated into two or more portions.

Once the portions of the resilient material 54 are separated, the textured model 52 is removed from the textured material. As shown in FIG. 9, the resilient material 54, defining half of a mold, can be a thin layer inlaid in a support structure 56 which reinforces the resilient material around and behind the cavity 58 defined by the

mold. In other embodiments, the resilient material 54 has a thickness sufficient to provide adequate stability for molding without requiring a supplemental support structure.

The mold is filled with a modeling material such as investment casting wax, using techniques known to those skilled in the art. When cured or hard, the textured wax pattern can be removed from the resilient mold by flexing the mold or peeling it away from the wax model, depending on the thickness and properties of the resilient material. The flexible mold can then be filled with wax again and again to replicate the model. Additional molds are readily fabricated using the original rapid prototype model. The textured wax models or patterns are subsequently subjected to known investment casting operations to make textured metal castings.

Yet another way to impart surface texturing to the wax model, instead of or in addition to the above described techniques, is to place one or more forms 60 having a textured face onto the surface of the resilient material 54 that defines a mold, textured face down toward the surface of the resilient material. When the mold is filled with wax, the textured form 60 or forms bond with the wax and thereby define a portion of the outer surface of the wax model. This technique is particularly well suited for creating a model with undercuts, corners, and other complex configurations. In an exemplary embodiment, the form 60 are forms are thin ceramic plaques having a selected pattern or texture.

Although the invention has been shown and described with respect to exemplary embodiments thereof, various other changes, omissions and additions in form and detail thereof may be made therein without departing from the spirit and scope of the invention.

Claims

1. A method of making a textured pattern for investment casting, comprising the steps of:

- a) creating a textured model;
- b) enveloping the textured model with a resilient material to create a resilient mold of the textured model;
- c) removing the textured model from the resilient mold;
- d) filling the resilient mold with investment casting wax to create a textured pattern; and
- e) removing the textured pattern from the resilient mold.

2. The method of claim 1, wherein the step of creating the textured model includes the steps of:

- a) creating a data file that defines a three-dimensional shape of at least a portion of an orthopedic implant;

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providing the data file to a rapid prototyping machine; and
creating a textured model representative of the data file with the rapid prototyping machine.

3. The method of claim 2, wherein the three-dimensional shape is configured to promote bone ingrowth. 5
4. The method of claim 2, wherein three-dimensional shape includes a plurality of layers each having a different porosity. 10
5. The method of claim 2, wherein three-dimensional shape includes a plurality of surface regions each having a different porosity. 15
6. The method of claim 2, wherein three-dimensional shape includes a plurality of layers each having a different configuration. 20
7. The method of claim 2, wherein the step of creating a data file includes accessing a computer assisted design program. 25
8. The method of claim 2, wherein the rapid prototyping machine creates a solid textured object.
9. The method of claim 1, wherein the resilient material includes silicone. 30
10. The method of claim 1, wherein the step of enveloping the textured model includes the step of defining a parting line. 35
11. The method of claim 1, wherein the step of removing the textured model from the resilient mold includes the step of dividing the resilient mold into two pieces. 40
12. The method of claim 1, wherein the resilient mold is joined to a rigid support.
13. The method of claim 1, wherein the textured model is removed from the resilient mold by flexing the resilient mold. 45
14. The method of claim 1, further comprising the step of placing a textured form on the surface of the resilient mold that defines the textured pattern, before the step of filling the resilient mold with investment casting wax. 50
15. A method of making a textured pattern for investment casting, comprising the steps of: 55

using computer assisted design software to create a data file that defines a three-dimensional

shape of at least a portion of an orthopedic implant;
providing the data file to a rapid prototyping machine capable of performing stereolithographic operations;

creating a textured model with a photocurable polymer, wherein the textured model is representative of the data file with the rapid prototyping machine;
enveloping the textured model with silicone to create a resilient mold of the textured model;
removing the textured model from the resilient mold;
filling the resilient mold with investment casting wax to create a textured pattern; and
removing the textured pattern from the resilient mold.

16. The method of claim 15, wherein the step of creating a data file includes the step of defining pores in at least a portion of the orthopedic implant, wherein the pores define openings in the surface of the implant that are in the range of 50 to 400 microns in diameter and wherein the pores have a depth in the range of 175 to 1000 microns.
17. The method of claim 16, wherein the step of creating a data file further includes the step of defining an implant surface having an open porosity in the range of 30% to 70%.
18. The method of claim 15, wherein the three-dimensional shape includes a plurality of surface regions each having a different porosity, the difference in porosity ranging from 10 to 20 percent.
19. The method of claim 15, further comprising the step of placing a textured form on the surface of the resilient mold that defines the textured pattern, before the step of filling the resilient mold with investment casting wax.

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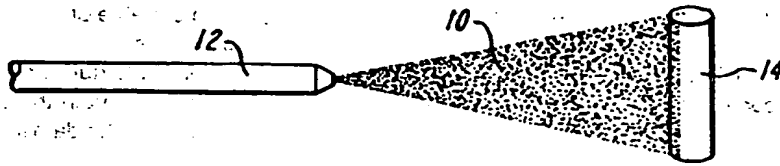


FIG. 1

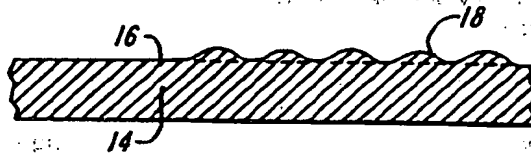


FIG. 2



FIG. 3

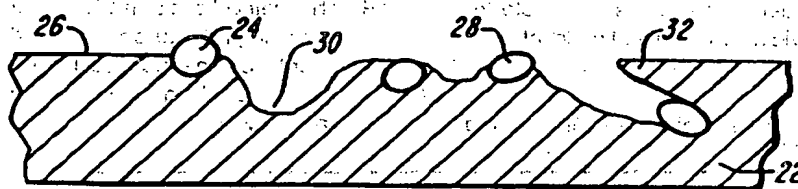
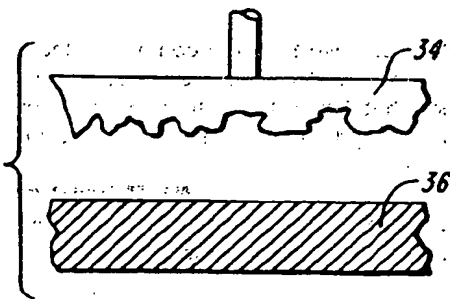


FIG. 4

FIG. 5



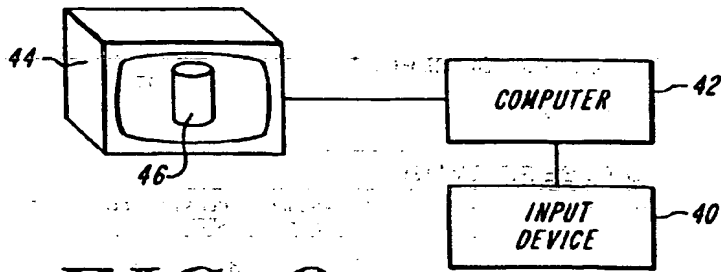


FIG. 6

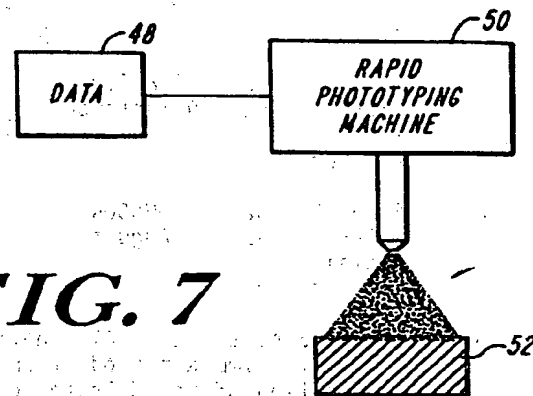


FIG. 7

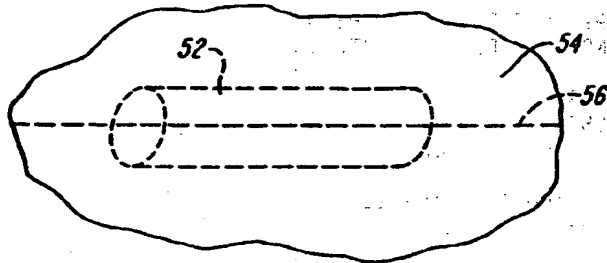


FIG. 8

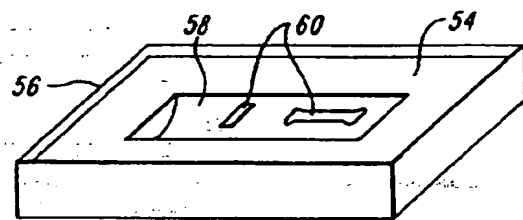


FIG. 9



European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 97 30 8331

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Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
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X	DE 41 02 256 A (ARTOS MED PRODUKTE) 30 July 1992 * column 2, line 5 - column 5, line 53 * * claims * * figures *	1-19	
A	EP 0 672 395 A (JOHNSON & JOHNSON PROFESSIONAL) 20 September 1995 * claims * * figures *	1-19	
A	EP 0 668 062 A (JOHNSON & JOHNSON PROFESSIONAL) 23 August 1995 * claims * * figures *	1-19	
A	WEEDER B.A. ET AL: "Alternative Methods for Custom Implant Production Utilizing a Combination of Rapid Prototyping Technology and Conventional Investment Casting" PROCEEDINGS OF THE 1996 FIFTEENTH SOUTHERN BIOMEDICAL ENGINEERING CONFERENCE, DAYTON, OH, USA, IEEE, 1996, NEW YORK, NY, USA, pages 555-557, XP002053926 * page 555, column 1, line 14 - column 2, line 29 * * page 557, column 2, line 1 - line 21 *	1-19	TECHNICAL FIELDS SEARCHED (Int.Cl.6) B22C A61F
The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
THE HAGUE	29 January 1998	Riba Vilanova, M	
CATEGORY OF CITED DOCUMENTS		<ul style="list-style-type: none"> 1. theory or principle underlying the invention 2. earlier patent document, but published on or after the filing date 3. document cited in the application 4. document cited for other reasons 5. members of the same patent family, corresponding documents 	
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DOCUMENTS CONSIDERED TO BE RELEVANT

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			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
The present search report has been drawn up for all claims.			
Place of search THE HAGUE		Date of completion of the search 29 January 1998	Examiner Riba Vilanova, M
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